Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20175217

Original Research Article

Awareness of pharmacovigilance and adverse drug reactions among second professional MBBS students of a medical college in Kerala, India

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Received: 11 October 2017
Accepted: 03 November 2017

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ABSTRACT

Background: Pharmacovigilance is the science and activities related to detection, assessment, understanding and prevention of adverse drug reactions (ADR). The major challenge faced by the pharmacovigilance programme of India is underreporting. It is mainly due to lack of awareness, knowledge, attitude and practice among health care professionals. The main objective of this study was to assess the knowledge, attitude and practices of second professional MBBS students towards ADR reporting and to provide a session on pharmacovigilance as an intervention to increase their awareness since they are the future budding doctors.

Methods: This questionnaire based study was conducted among 158 second professional MBBS students of Travancore Medical College, Kollam, Kerala. A pretest was conducted using the questionnaire followed by which a two-hours session on ADR reporting and Pharmacovigilance was given. A posttest was done with the same questionnaire. The response of the KAP questionnaire were analysed separately for pretest and posttest in percentages and based on scores and was compared.

Results: Out of the158 students participated all the students successfully completed the questions of both pretest and posttest within stipulated time frame. In pretest 3 (1.9%), 101 (64%), 43 (27.1%) candidates were categorized to excellent, good and poor respectively. In posttest 155 (98.1%), 3 (1.9%) were in excellent and good category respectively. There was not even a single candidate in poor category. There was a marked increase in the knowledge and awareness of the students after the two hours intervention session on ADR reporting and pharmacovigilance which was statistically significant (p= 0.001).

Conclusions: This study revealed the awareness of second professional MBBS students towards ADR reporting and Pharmacovigilance in our institution and also clearly showed the importance of early sensitization through educational interventions, which improved the KAP in pharmacovigilance in them. Educating medical students will improve the challenge of underreporting of ADRs and will increase the numbers of ADRs reported in our country.

Keywords: Adverse drug reaction (ADR), Pharmacovigilance, Pharmacovigilance programme of India (PvPI)

INTRODUCTION

In the era of modern medicine drugs are very commonly used. Usage of drugs not only results in beneficial effects but also may result in some unexpected or noxious effects commonly known as adverse drug reactions (ADR). No drug is exempt from the potential of ADR. As defined by the WHO ADR is any noxious, unintended and undesired effect of the drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy of a disease or the modification of the physiological state.[1] Pharmacovigilance is the branch of pharmacology which deals with ADR.

As the name suggests pharmacovigilance is derived from the Greek word "pharmakon" which means a drug and from the Latin word "vigilance" which means watchful or careful. WHO has defined pharmacovigilance as the

science and activities relating to detection, assessment, understanding and prevention of the adverse effects.[1] ADRs are one of the leading causes of morbidity and mortality at present. It has been revealed from the previous studies that around 2.9-5.6% of all admissions are due to ADRs and almost 35% of hospitalized patients experience an ADR during their stay in hospital.[2]

The history of pharmacovigilance dates back to the thalidomide tragedy which happened in 1960's. It was introduced as a hypnotic but was extensively used as an effective remedy for pregnancy related morning sickness without adequate safety data in pregnancy which resulted in birth of thousands of congenitally malformed babies. FDA was keen in introduction of strict monitoring, testing and approval of drugs.[3]

The challenge comes in detecting the ADRs in timely manner. Animal toxicity studies and clinical trials are done to assure the safety of drugs, but still we all know the limitations in identifying the ADR during clinical trials and before a drug is marketed. Pharmacovigilance plays a key role in identifying the unnoticed ADRs. It is the post marketing studies and spontaneous reporting of ADR that fill the void in the information we possess, especially with respect to the long-term effects and the use in the patient population with comorbidities and polypharmacy. The use of medicines for therapy will continue and may result in ADRs, sometimes even serious and lethal. Pharmacovigilance will be helpful in reducing the mortality and morbidity due to ADRs in future.

Uppsala monitoring centre (UMC) in Sweden is the WHO collaborating centre internationally for ADR monitoring. It works by collecting, assessing and communicating information to the National pharmacovigilance centres of the member countries in regard to the benefits, harm, effectiveness and risks of the drugs.[4] UMC developed and maintains a global individual case safety report database known as Vigibase on behalf of WHO.[5]

In India, the Pharmacovigilance programme (PvPI) was initiated in 2010 upholding the mission to safeguard the health of the Indian population by ensuring that the benefits outweigh the risks associated with the use of medications.[6]For the implementation of the program and to transform the concept of pharmacovigilance into practice , ADR monitoring centres (AMC) have been set in various parts of the country under the PvPI to enhance and ensure the safety of patients.[7] Presently there are around 250 AMCs across the country attached to medical colleges and hospitals. AMC of Travancore medical college, Kollam, Kerala is one of the recently approved AMC under PvPI. Even after putting best efforts by the PvPI, still the reporting of ADRs is less. Underreporting of ADRs can delay detection of serious ADRs and can produce a negative impact on the public health which may lead to prolong hospital stays and financial loss. Underreporting still remains as one of the major obstacles for the success of PvPI.[8]Underreporting of ADR may be due to lack of awareness regarding the necessity of ADR reporting, lack of knowledge, attitude and practice among healthcare professionals.[9]

In the present scenario along with providing the knowledge and practice for reporting to the health care professionals it is more important to make the upcoming medical graduates who are the future doctors aware about the significance of ADR reporting, regarding pharmacovigilance and the necessity of PvPI. This questionnaire based study was hence conducted to assess the knowledge, attitude and practice of second professional MBBS students in our institution and to make them more aware, as an intervention, we conducted a session on ADR reporting and Pharmacovigilance for them.

METHODS

This is a questionnaire based study done among 158 students in Travancore medical college, Kollam, Kerala. The approval for conducting the study was obtained from the institutional ethics committee and informed consent was obtained from all the participants. The study participants were second professional MBBS students. A Questionnaire containing 20 questions was given to the students and were asked to answer it within 20 minutes. The questionnaire was developed by modifying the questionnaires obtained from previous studies. Questions 1-14 were multiple choice questions with 4 options and were to assess the knowledge of the students. Each correct answer was given 1 mark and wrong answer was given zero mark. There was no negative marking. The questions from 15-20 were questions replying yes or no which was used to assess the attitude and practice. This was considered as a pretest data. Following the pretest a 2 hours session on pharmacovigilance and ADR reporting was taken for the participants. There was active interactions and the doubts regarding pharmacovigilance and the necessity of ADR reporting was conveyed during the session. A post test was conducted using the same questionnaire. The data entry was done on excel sheet. The data of both pretest and posttest was analysed and compared using paired T test and using SPSS16. The data was categorized based on the performance into three. Those who scored between 0-5 were considered as poor, who scored between 6-10 as good and above 11 as excellent for both pretest and posttest.

RESULTS

Out of the 158 students participated all the students successfully completed the questions of both pretest and posttest within stipulated time frame. Of the students 51 were males and 107 were females. The results of the knowledge based multiple choice questions in pretest and posttest are tabulated in Table 1.

The comparison of performance based on scoring in pretest and posttest is depicted in Figure 1. They were

grouped based on the scores into poor (sores <5 marks), good (scores from 6-10 marks) and excellent (scores >1 marks). In pretest 3 (1.9%), 101 (64%), 43 (27.1%) candidates were categorized to excellent, good and poor respectively were as in posttest there was not even a single candidate who scored less than 5 marks. 155 (98.1%) candidates scored 11 or more than 11 marks and the remaining 3 (1.9%) were categorized to good category.

Table 1: Results of the Knowledge based multiple choice questions in pretest and post-test.

Questions	Pre-test (N = 158)	Post-test (N = 158)
Pharmacovigilance is the study that relates to	139(88.0%)	158(100.0%)
Pharmacovigilance includes	61(38.6%)	136(86.1%)
National Pharmacovigilance Programme in India is governed by	68(43.0%)	148(93.7%)
The national coordinating centre for Pharmacovigilance in India is at	91(57.6%)	151(95.6%)
The international centre for ADR monitoring is located in	97(61.4%)	150(94.9%)
Which one of the following is the "WHO online database" for reporting ADRs	37(23.4%)	157(99.4%)
The healthcare professionals responsible for reporting ADR in a hospital is/are	131(82.9%)	157(99.4%)
Life-threatening ADR are those which result in	109(69.0%)	153(96.8%)
Rare ADRs can be identified in the following phase of a clinical trial	113(71.5%)	143(90.5%)
Regarding classification of ADR's, the correct option is	122(77.2%)	150(94.9%)
What type of ADRs to be reported	116(73.4%)	153(96.8%)
Activities involved in pharmacovigilance include	139(88.0%)	155(98.1%)
Measures to be taken when ADR is suspected	142(89.0%)	155(98.1%)
Which of the following scales is commonly used to assess the causality of an ADR's	34(21.5%)	158(100.0%)

There was a marked increase in the knowledge and awareness of the students after the two hours intervention session on ADR reporting and pharmacovigilance which was statistically significant (Table 2). The responses in percentages for the yes or no based questions for assessing the attitude and practice is shown in Table 3.

Table 2: Association between knowledge of pharmacovigilance among students in pretest and post-test.

Variable	N	Mean Score	Std. deviation	T value	p value
Pre-test knowledge	158	8.85	2.462	21.254	0.001*
Post-test knowledge	158	13.44	1.013		

p value calculated by dependent samples t test, p <0.05 considered as significant.

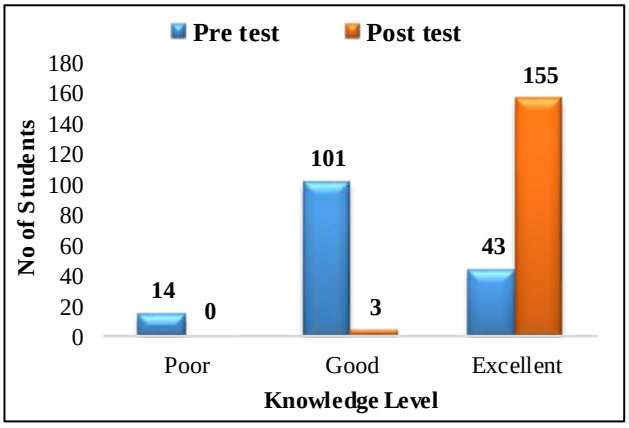

Figure 1: Results based on the scores obtained by the students based on knowledge questions in pretest and posttest (poor = <5 marks, good = 6-10 marks, excellent = >11 marks)

DISCUSSION

Adverse drug reaction surveillance and pharmacovigilance is done with the aim to ensure rational therapy and ensure patient safety. ADRs cannot be totally avoided since it comes as part and parcel of the therapy, but the awareness regarding ADR and the necessity of pharmacovigilance can be imparted to all, especially for the medical students who are the future budding doctors. ADR monitoring and reporting is still in infancy stage even after the strenuous efforts by the PvPI.

This questionnaire based study done in 158 second professional MBBS students was not only done to assess the KAP towards ADR reporting and pharmacovigilance but also to provide an awareness and impart knowledge regarding pharmacovigilance so that they will be practicing the same in future.

The pretest results of our study showed that 139(88%) students knew pharmacovigilance is a study related to detection, assessment, understanding and prevention of adverse effects which was 71%, 87% and 70.8% respectively in the previous studies done.[10-12] For the question pharmacovigilance includes the correct response was given by 61 (38.6%) students were as it was 30.5% in the study done by Tabassum et al, 68 (43%) students knew the correct answer regarding the governing body of the national pharmacovigilance programme in India were as it was 57%, 24.6% and 51% respectively in previous studies.[10-12]

Location of National coordinating centre of PvPI at Ghaziabad was known to 91 (57.6%) of students in our study which was 60% and 51% respectively in previous studies.[10,11] International centre for ADR monitoring, Uppsala Monitoring centre (UMC) at Sweden was known to 97 (61.4%) of students in the present study which was 57%, 50% and 50.7% respectively in previous studies.[10-12] WHO online database, vigibase was known only to 37 (23.4%) in our study which was even lower in the previous studies (11% and 16.4%).[11,12]

Table 3: Results of the attitude and practice based yes or no questions in pretest and post-test.

Questions	Pre-test (N = 158)		Post-test (N = 158)	
	Yes	No	Yes	No
ADR and ADE are same	36(22.8%)	122(77.2%)	24(15.2%)	134(84.8%)
Do you think ADR monitoring and reporting will benefit patients	152(96.2%)	6(3.8%)	158(100%)	0(0%)
Is ADR reporting a professional obligation	91(57.6%)	67(42.4%)	113(71.5%)	45(28.5%)
Do you know how to fill an ADR form	80(50.6%)	78(49.4%)	152(96.2%)	6(3.8%)
Are you aware of any drug/drugs that have been banned or withdrawn from market	128(81.0%)	30(19%)	147(93.0%)	11(7%)
Do you believe that topic of Pharmacovigilance is well covered in your curriculum	114(72.2%)	44(27.8%)	154(97.5%)	4(2.5%)

131 (82.9%) of the students were aware that all health care professionals like doctors, nurses and pharamacists can report ADR but it was 60%, 47% and 73.8% respectively in the previous studies done.[10-12]

Death, hospitalization and prolongation of hospitalization were all considered as life threatening ADRs by 109(69%) of our students which was almost similar to the results of previous study (67.1%).[12]

113 (71.5%) of our students were aware about the phase of clinical trial in which rare ADRs were identified which was just 26.13% in the previous study.[13] Other knowledge related questions assessed by us was regarding the classification of ADRs, types of ADRs to be reported, activities involved in pharmacovigilance, measures to be taken when ADR is suspected and regarding the scales for the assessment of causality of an ADRs which was not assessed in the above-mentioned studies.

122 (77.2%) of our students answered no for the question whether ADR and ADE are same which was 73.1% in the previous study.[12] ADR monitoring and reporting was considered to be beneficial to the patients by 152 (96.2%) of the students in the present study which was 99.2% in the previous study.[12] ADR reporting was agreed as a professional obligation by 91 (57.6%) of our students which was 42% and 45% in studies done by Nadeem et al, Dhananjay et al.[10,11] 80 (50.6%) of our students knew how to fill an ADR form but only 16.4% of the students knew reporting of ADR in previous study.[12]

Most of our students were aware about the drugs withdrawn from market (128-81%) the results were almost similar to previous studies. 114 (72.2%) of our students believed that the topic of pharmacovigilance is well covered in their curriculum but only 41% students agreed with that in the previous study.[12]

The strength of our study compared to the other above-mentioned studies was that we have conducted an intervention session and a posttest on ADR reporting and pharmacovigilance to make them more aware about the necessity of ADR reporting and their role in supporting the PvPI as future doctors.[10-13] The session covered most of the aspects of ADR reporting and pharmacovigilance including how to fill and ADR form and how to report it to the AMC. Our study also demonstrates that educational interventions can increase awareness of pharmacovigilance among medical students.

Limitations of the study includes this is a study conducted among 158 second professional MBBS students only based on the convenience sample which involves students coming to department of Pharmacology. The sample size is limited and was restricted to second year students. The awareness should be carried on to all medical students, interns and students from other allied medical sciences like nursing and pharmacy students.

CONCLUSION

The present study identified the awareness of KAP in second professional MBBS students towards ADR reporting and pharmacovigilance. We provided an intervention session on ADR reporting and Pharmacovigilance which motivated them to improve their knowledge, attitude and practice in future in aspect of ADR reporting and made them aware about their role in supporting PvPI and to ensure the safety of medications in patients. It's our duty to encourage ourselves and the future health care professionals to report ADR and overcome the main challenge of under reporting of ADR. We recommend all the senior health care professionals to implement educational interventions to their students and to extent the importance of the pharmacovigilance in the curriculum for medical students which will improve knowledge of budding doctors.

ACKNOWLEDGEMENTS

Authors would like to thank all our students who have spared their valuable time and participated in this study, the institutional ethics committee and the management for their support. We sincerely acknowledge Mr. Sony Simon, who helped us in doing statistics of the study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Aslam AP, Shajahan J, Purushothaman S. Awareness of pharmacovigilance and adverse drug reactions among second professional mbbs students of a medical college in Kerala, India. Int J Basic Clin Pharmacol 2017;6:2911-5.